RECEIVED
CENTRAL FAX CENTER

DEC 0 4 2007

REMARKS

Claims 1-69 are pending. Claims 9, 10, 32, 33, and 58 have been withdrawn. By this Amendment, claims 1, 13, 23, 28, 36, 41, and 53 are amended and new claims 70-72 are added. This corrected Amendment is in response to the Communication dated November 15, 2007. The Examiner is thanked for the opportunity to correct the record. Please note: The extra claim fee of $150.00 was charged to our deposit account on August 23, 2007.

Independent claim 1 was amended to further clarify the structural aspects of the claims limitations, including specifying that "the hydrogel, at the substantially less than equilibrium level of hydration, having dimensions to pass through a tube having an inner diameter of no more than about 1.5 mm", with support being found in the specification at, e.g., Example 12. Further, the term "size" was used instead of "shape" to specify the structural aspects of what is claimed.

Claim 13 was amended to eliminate certain embodiments and to clarify that what is claimed is a unitary hydrogel and not, e.g., a plurality of beads.

Claims 23, 28, and 36 were amended to clarify and emphasize the structural-dimensional aspect of what is claimed.

Independent claim 41 was amended to further clarify the structural aspects of the claims limitations, including specifying that "the hydrogel, at the substantially less than equilibrium level of hydration, having dimensions to pass through a tube having an inner diameter of no more than about 3 mm", with support being found in the specification at, e.g., Example 9. The preamble "A medical implant for use in a lumen or void of a body that is created as by a percutaneous catheter puncture for access to an artery for exchange of catheters required through the puncture" is supported at, e.g., page 19 lines 19-25. This type of procedure is well-known in the arts, e.g., as evidenced by U.S. Pat. No. 5,350,399 which describes these procedures as

producing wound of about 1.5 to about 5.0 mm (column 1 line 44), which is consistent with the amendments of the independent claims to recite certain sizes of hydrogels.

Independent claim 53 was amended to further clarify the structural aspects of the claims limitations, including specifying that "the hydrogel having a size before implantation for passage through an inner diameter of no more than about 4 mm of a catheter or hollow needle into the body" with support being found in the specification at, e.g., Examples 1 or 9.

New claims 70-72 each depend on one of the independent claims and recite "wherein the hydrogel comprises a cylindrical roll", as supported in the specification at, e.g., as in Example 6 which refers to a "carpet roll", with the term "roll" referring to a quantity rolled into a cylinder, as is familiar in the uses of carpet or cloth. Certainly nothing in the references cited by the Patent Office teaches or suggests this limitation.

REJECTIONS UNDER 35 U.S.C. §102(e) IN LIGHT OF U.S. PAT. NO. 5,843,743

Claims 1-8, 11-15, 20-28, 34-38, 41-50, 52-54, 59-60, and 64-69 have been rejected under 35 U.S.C. §102(e) as being anticipated by Hubbell et al. (U.S. Pat. No. 5,843,743, referred to as the '743 patent). With respect to the properties of hydration and shape, the Office Action takes the position that such properties must be inherently possessed by the compositions of the '743 patent, since they are the same as what is claimed. The Office Action also takes the position that certain claims require creation of a lumen and its filling with swelled gel, with such limitations being intended uses with no patentable weight in the present device claims. The Office Action takes note of previous arguments made by Applicant that the claimed percent volumetric expansion is not disclosed in the prior art such that the Patent Office's record fails to show that this property is in the prior art; but the Office Action takes a counter-position and argues that the claimed gel is identical to the gel of the '743 patent so that such claims to expansion are anticipated.

Swellability

In response to the Office Action's position on swellability, it is respectfully submitted that the Patent Office has failed to meet its burden of showing that the claimed swelling is present. The legal standard requires the Patent Office to show that the prior art *taught or suggested* making the hydrogels with the claimed amount of swelling in the claimed dimensions. An argument that the '743 patent materials *could have been* made with the claimed amount of swelling would be inadequate. The Office Action assumes that the claimed materials are "identical" to the '743 materials and concludes that they "inherently" have the same swellability. If the swellability is truly inherent, however, then the '743 materials always have a certain swellability: the Patent Office is requested to state what is the inherent swellability of those materials? Presumably the '743 materials could be made with a range of swellability outside of the claimed swelling ranges, for instance by controlling the degree of crosslinking in the hydrogel and/or its solids content. This assumption of identity and inherency is unreasonable: the Patent Office is requested to state a basis for this assumption.

Moreover, the '743 patent is apparently limited to photopolymerizable macromers, e.g., acrylates, as per column 5 lines 24-34. This condition explicitly excludes, among other things, the claim to electrophile-nucleophile reactions in claim 25.

The Patent Office is requested to withdraw the rejection for these reasons. As explained below, however, there are further reasons for withdrawing the rejection.

Dimensional limitations

In general, the claims have been amended to emphasize and clarify their structural limitations; the Patent Office is requested to acknowledge the patentable weight of these limitations and withdraw the rejection.

By way of overview, one of the problems with the Office Action's rejection is that the '743 patent does not disclose dehydration and swelling except as incidental to testing of physical properties, with those tests requiring a peculiar "dogbone" shape that would not reasonably be expected to function as claimed, i.e., seal and occlude (claim 1) or expand/occlude (claims 41/53). Dogbones are used for devices that need a relatively large end-area to grip and a smaller area in the middle having carefully controlled dimensions for testing: hence, the term "dogbone". The testing was done on a Instron-like device that clamps onto the relatively large ends of the dogbones and pulls the sample apart while the events at the narrow neck of the dogbone are observed and measured.

Specifically, the Patent Office points to column 26 lines 24-25 of the '743 patent as providing the claimed hydration and swelling. This passage, which is part of Example 17, states that "the samples were then oven-dried to a constant weight extracted and reswelled as mentioned before." Example 17 explains that "dogbone shapes" of gels as in Example 15 were made, the gels were oven-dried, and extracted in methylene chloride (column 25 line 62- column 26 line 6). The dogbone samples were cut from a slab in the shape of a dogbone with wide regions at both ends and a narrower long region in the middle. The samples were 20 mm long and 2 mm wide at their narrowest portions, with a thickness of 0.5 to 1.75 mm (column 24 lines 53-54). The samples seem to have been cut from slabs having a dimension of about 40 x 10 x 5 mm (column 24 line 40) and there is no evidence in the Office Action that the samples would pass through a tube of 1.5, 3, or 4 mm, as in amended independent claims 1, 41, or 53, respectively. Further, claim 13 and new claims 70-72 list specific shapes that are not in the cited reference.

Accordingly, since amended claim 1 requires that "the hydrogel, at the substantially less than equilibrium level of hydration, having dimensions to pass through a tube having an inner

diameter of no more than about 1.5 mm", and there is no evidence that the cited reference teaches such a dimension, withdrawal of this rejection is requested.

Similarly, independent claim 41 as amended requires a size to occlude a lumen or void created as by a percutaneous catheter puncture for access to an artery for exchange of catheters required through the puncture, a familiar procedure resulting in a typical range of wound shapes and sizes, as is known to artisans in this field, e.g., as in U.S. Pat. No. 5,350,399 (submitted in the Supplemental Information Statement faxed August 22, 2007) and as in the Application at pages 19-20 in the section entitled "Wound Closure". Such wounds require a range of shapes; it is unknown how the dogbone of the cited art would supply such a shape. The claimed limitations of passage through a 3 mm tube as in claim 41 speaks to the required shape and provides additional structure to the claim.

Similarly, independent claim 53 as amended also has additional structure that requires a size before implantation for passage through an inner diameter of no more than about 4 mm of a catheter or hollow needle into the body. This limitation requires very detailed dimensional characteristics that are not provided by the cited references.

REJECTIONS UNDER 35 U.S.C. §103(a) IN LIGHT OF U.S. PAT. NOS. 5,843,743 AND 4,948,575 TO COLE ET AL.

Claims 1-8, 11-31, 34-57, and 59-69 were rejected under 35 U.S.C. §103(a) as being unpatentable over the '743 patent and in view of Cole et al. (U.S. Pat. No. 4,948,575, referred to as the '575 patent).

As already explained, the '743 patent does not teach all of the claimed elements. The '575 patent does not make-up for this defect. Withdrawal of this rejection is requested. Additional grounds for allowing the claims are discussed below.

The Patent Office has taken the position that Cole's teaching against the combination of the '743 and the '575 is "merely cautionary". The Patent Office seems to rely on impermissible hindsight to make this combination. The Patent Office insists that the combination is legitimate because it should be possible to pick the claimed elements out of the '575 references. What is necessary, however, is for the Examiner to consider what is fairly taught by the references. The Applicant's position against the combination is repeated in detail below.

In brief, the '575 patent teaches that dimensionally stable foams are what is made and are what is **required** with the explanation that swelling is **to be avoided**. The proposed combination requires *changing the principle of operation* of Cole by using its techniques to make a dimensionally unstable hydrogel, which is the *opposite* of the stable hydrogel that it teaches.

Cole teaches away from having a substantially less than equilibrium level of hydration for undergoing a volumetric expansion to occlude a lumen or void after swelling with a fluid from the body. Cole teaches that "If the dressing swells upon the absorption of fluids, this lack of dimensional stability may severely undercut the utility of these dressing for packing deep, heavily exuding wounds." Cole column 2 lines 45-48. Consequently, "When applied in or on a wound, the foaming action gently expands the dressing material conforming it to the shape of the cavity in, or the surface on, which it is applied. The dressing material subsequently cures to a **dimensionally stable hydrogel** foam which exactly fits the wound." Cole, column 3, lines 19-25, emphasis added. The dimensionally stable non-expanding hydrogels taught by Cole are what is **not** claimed - this teaching **points the artisan away from what is claimed.**

REQUEST FOR RELIEF

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

Curtis B. Herbert, Ph.D., Esq.
Registration No. 45,443

Customer No. 62274
Dardi & Associates, PLLC
US Bank Plaza, Suite 2000
220 South 6th Street
Minneapolis, Minnesota 55402
Telephone: (612) 305-1038